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Certifier J. Cooke

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0233]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Sunscreen Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following conditions as part of FDA's ongoing review of over-the-counter (OTC) drug products: Amiloxate (isoamyl p-methoxycinnamate), up to 10 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; enzacamene (methyl benzylidene camphor), up to 4 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; and octyl triazone, up to 5 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients. FDA has reviewed time and extent applications (TEAs) for these conditions and determined that they are eligible for consideration in it's OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether these conditions can be generally recognized as safe and effective (GRAS/E) for their proposed OTC use.

DATES: Submit data, information, and general comments by [*insert date 90 days after date of publication in the* **Federal Register**].

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ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term "condition" means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug

monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEAs that the agency reviewed (Refs. 1, 2, and 3) and FDA's evaluation of the TEAs (Refs. 4, 5, and 6) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document.

II. Request for Data and Information

The conditions amiloxate, up to 10 percent; enzacamene, up to 4 percent; and octyl triazone, up to 5 percent, as sunscreen single active ingredients and in combination with other existing monograph sunscreen active ingredients will be evaluated for inclusion in the monograph for OTC sunscreen drug products (21 CFR part 352). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of these single active ingredients for FDA to determine whether they can be GRAS/E and not misbranded under recommended conditions of OTC use. Additional data (from human clinical studies) should be included to establish the safety and effectiveness of combination sunscreen drug products containing amiloxate, enzacamene, or octyl triazone with other existing sunscreen monograph active ingredients.

Interested persons should submit comments, data, and information to the Divison of Dockets Management (see **ADDRESSES**) by [*insert date 90 days after the date of publication in the* **Federal Register**]. Three copies of all comments, data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting

information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under § 10.30 (21 CFR 10.30).

III. Marketing Policy

Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for amiloxate (isoamyl p-methoxycinnamate) submitted by Haarmann & Reimer Corp. dated August 14, 2002.

2. TEA for enzacamene (methyl benzylidene camphor) submitted by Buchanan Ingersoll on behalf of Merck KGaA dated August 21, 2002.

3. TEA for octyl triazone submitted by Morgan, Lewis & Bockius LLP on behalf of BASF AG dated August 21, 2002.

4. FDA's evaluation and comments on the TEA for amiloxate.

5. FDA's evaluation and comments on the TEA for enzacamene.

6. FDA's evaluation and comments on the TEA for octyl triazone.

Dated: 7/5/03

July 5, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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